IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF WISCONSIN

SHANON SCHMIDTKNECHT individually and WILLIAM SCHMIDTKNECHT individually and as Special Administrator of the Estate of COLE SCHMIDTKNECHT,

Plaintiffs,

v.

OPTUMRX, INC.,

and

WALGREEN CO., a/k/a WALGREENS BOOTS ALLIANCE, INC., d/b/a WALGREENS PHARMACY

and

WALGREENS PHARMACY,

Defendants.

Case No. 1:25-cv-0093

DEFENDANT OPTUMRX, INC.'S ANSWER AND DEFENSES TO PLAINTIFFS' AMENDED CIVIL ACTION COMPLAINT

Defendant OptumRx, Inc. ("Optum Rx"), by and through its undersigned counsel, answers and asserts defenses to Plaintiffs' Amended Civil Action Complaint as follows:

PARTIES

1. Plaintiff Shanon Schmidtknecht is an adult citizen of the State of Wisconsin, residing therein at W10520 Tipperary Road, Poynette, Wisconsin 53955.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 and therefore denies the same.

2. Plaintiff William Schmidtknecht is an adult citizen of the State of Wisconsin, residing therein at W10520 Tipperary Road, Poynette, Wisconsin 53955.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore denies the same.

3. Cole Schmidtknecht was born on March 18, 2001, and died on January 21, 2024.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies the same.

4. Cole Schmidtknecht was an adult citizen of the State of Wisconsin, who formerly resided therein at 1426 West Weiland Lane, Appleton, Wisconsin 54914.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and therefore denies the same.

5. William Schmidtknecht was appointed as the Special Administrator of the Estate of Cole Schmidtknecht by the Circuit Court of Outagamie County, Wisconsin, on January 6, 2025.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 and therefore denies the same.

6. Defendant OptumRx, Inc. is a corporation incorporated in the state of California with its corporate headquarters located at 2300 Main Street, Irvine, California 92614.

ANSWER: Optum Rx admits that it is a corporation incorporated under the laws of the State of California and that it has a facility at 2300 Main Street, Irvine, California 92614. Optum Rx denies the remaining allegations in paragraph 6.

7. Defendant OptumRx, Inc. will be referred to herein as "OptumRx."

ANSWER: Optum Rx admits the allegations in paragraph 7.

8. Defendant Walgreen Co., a/k/a Walgreens Boots Alliance, Inc., d/b/a Walgreens Pharmacy, is a corporation incorporated in the state of Delaware with its principal place of business and headquarters at 108 Wilmot Road, Deerfield, Illinois 60015.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 and therefore denies the same.

9. Defendant Walgreen Co., a/k/a Walgreens Boots Alliance, Inc., d/b/a Walgreen Pharmacy, is a retail pharmacy with locations across the country.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 and therefore denies the same.

10. Defendant Walgreens Pharmacy is one such retail pharmacy, located at 729 West Northland Avenue, Appleton, Wisconsin 54914.

ANSWER: Optum Rx admits that a retail pharmacy is located at 729 West Northland Avenue, Appleton, Wisconsin 54914. Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 and therefore denies the same.

11. Defendant Walgreens Co., a/k/a Walgreens Boots Alliance, Inc., d/b/a Walgreens Pharmacy, and defendant Walgreens Pharmacy will be collectively referred to herein as "Walgreens Defendants."

ANSWER: Optum Rx admits the allegations in paragraph 11.

JURISDICTION AND VENUE

12. Federal jurisdiction in this action is predicated upon diversity of citizenship under statutory authority of 28 U.S.C. § 1332. The amount in controversy exceeds \$75,000.00.

ANSWER: Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 and therefore denies the same.

13. For purposes of diversity under 28 U.S.C. § 1332, Plaintiffs are citizens of the State of Wisconsin, Defendant OptumRx is a citizen of the State of California, and Walgreens Defendants are citizens of the States of Delaware and Illinois.

ANSWER: Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx admits that for purposes of diversity jurisdiction it is a citizen of the State of California and not a citizen of the State of Wisconsin and lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 and therefore denies the same.

14. Venue is proper in the Eastern District of Wisconsin pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this District with respect to the civil action in question.

ANSWER: Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies that its conduct in this District gave rise to Plaintiffs' alleged claims in this case and lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 and therefore denies the same.

OPERATIVE FACTS

THE OLIGOPOLY OF PHARMACY BENEFIT MANAGERS

15. In the modern U.S. healthcare system, Pharmacy Benefit Managers (hereinafter "PBMs") are entities that act as middlemen between health insurers, prescription drug companies, and pharmacies.

ANSWER: Optum Rx admits that the services provided by some PBMs, including Optum Rx, include administering the pharmacy benefits and formularies their plan sponsor clients choose to adopt. These services can include establishing and organizing networks of pharmacies where plan participants can get prescriptions filled and negotiating rebates and discounts from

prescription drug manufacturers to lower the cost of prescription drug coverage for the plan sponsors and their participants. Each client retains the sole authority to design and administer its own plan, including the contents of its formulary, and no formulary becomes part of a client's offered benefit design unless and until the client adopts it. Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 and therefore denies the same.

16. The nation's three largest PBMs oversee the fulfillment of over 79% of drug prescriptions in the United States, belonging to over 200 million Americans.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 and therefore denies the same.

17. One of these three giant PBMs is United Health Group's subsidiary, OptumRx. OptumRx services claims for over 66 million people nationwide. Their market share has been steadily rising over the past decade as the industry has consolidated into a powerful oligopoly.

ANSWER: Optum Rx admits that it is a subsidiary of UnitedHealth Group Incorporated, that it provides pharmacy benefits management ("PBM") services to health benefits providers, large national employer plans, unions and trusts, purchasing coalitions and public-sector entities, with more than 66 million members nationwide. Optum Rx denies the remaining allegations of paragraph 17.

18. PBMs artificially drive up healthcare costs for Americans in a myriad of ways, such as forcing patients to fill prescriptions for more expensive drugs even when cheaper alternatives exist for the same conditions and setting artificial requirements that patients go on so-called "step- up" regimens, where they are required to try more expensive drugs for a certain period of time dictated by the PBM, before they are permitted to receive the medication their doctor chose.

ANSWER: Optum Rx denies the allegations in paragraph 18.

A significant portion of Americans do not have emergency savings and cannot afford an unexpected expense of over \$400.1 One study found that 27% of adults have no emergency savings at all.2

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and therefore denies the same.

20. According to an interim staff report released in July of 2024 by the Federal Trade Commission as part of the agency's ongoing investigation into the growing and consolidating PBM industry, the FTC stated that PBMs "wield enormous power and influence over patients" access to drugs and the prices they pay. This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs."

The referenced document is the best evidence of its own text and Optum Rx ANSWER: denies any allegations inconsistent with its full text, including the dissents to that text from a then commissioner of the FTC. Optum Rx denies any remaining allegations in paragraph 20.

PBMS DICTATE PATIENTS' MEDICATIONS BASED ON THEIR OWN FINANCIAL **INTERESTS**

21. Advair Diskus is a brand name for a corticosteroid inhaler that is used to prevent and control symptoms of asthma.

Optum Rx admits that Advair Diskus is a brand name prescription ANSWER: medication used to treat asthma.

¹ See PR NEWSWIRE, 37% of Americans can't afford an emergency expense over \$400, according to Empower research, https://www.prnewswire.com/news-releases/37-of-americans-cant-afford-an-emergencyexpense-over- 400-according-to-empower-research-302187157.html; CNBC, Personal Finance 44% of Americans can't pay an unexpected \$1,000 expense from savings, https://www.cnbc.com/2024/01/24/many- americans-cannot-pay-for-an-unexpected-1000-expense-hereswhy.html

² See BANKRATE, Bankrate's 2024 Annual Emergency Savings Report, https://www.bankrate.com/banking/savings/emergency-savings-report/

22. As the fall of 2023 approached, OptumRx changed its formulary of covered drugs for the coming year and determined that it would no longer cover Advair Diskus or its generic equivalents.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor clients. Optum Rx admits that each client retains the sole authority to design and administer its own plan, including the contents of its formulary, and no formulary becomes part of a client's offered benefit design unless and until the client adopts it. As part of the formulary management services it offers to its customers, OptumRx makes available standard formulary offerings that are derived from clinical input driven by an independent Pharmacy & Therapeutic ("P&T") Committee. Some clients choose to adopt one of Optum Rx's standard formularies as their own.³ To help promote high-quality, cost-effective formulary design and management for clients choosing an Optum Rx formulary, Optum Rx's P&T Committee provides unbiased, evidence-based review and appraisal of new and existing drugs and their role in therapy. The P&T Committee, comprised of independent practicing physicians and pharmacists who are free from conflicts of interest, evaluates drugs based on scientific evidence, including peer-reviewed medical literature, well-established clinical practice guidelines, and pharmacoeconomic data.

Optum Rx admits that in or around September 2023, it decided to change the placement of brand Advair Diskus on the Optum Rx Premium Formulary, effective January 2024, when that drug would no longer be covered, and the Kriete Plan adopted the Premium Formulary for 2024. Optum Rx denies any remaining allegations in paragraph 22.

23. Instead, OptumRx would only cover Advair HFA or Breo Ellipta, two newer, brand drugs, whose manufacturer had paid OptumRx substantial kickbacks (euphemistically called "rebates" and/or "compensation") in exchange for their favorable placement on OptumRx's updated

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³ Not all plan sponsors delegate formulary management to the Optum Rx P&T Committee. The fully-insured UnitedHealthcare plan sponsored by Kriete Trucking through which Mr. Schmidtknecht had benefits prior to 2024 utilized a standard formulary recommended by the UHC P&T Committee, not the Optum Rx P&T Committee.

formulary, while excluding Advair Diskus and its generic equivalents.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor clients. Optum Rx admits that it decided to change the placement of brand Advair Diskus on its Premium Formulary in light of the availability of other therapeutically-equivalent drugs on the formulary, which provided safe and effective treatment alternatives along with a better overall value for plan sponsors based on rebates their manufacturers agreed to pay, reducing the net cost to plan sponsors of the rebated drugs. Optum Rx denies that any such payments are kickbacks. Optum Rx denies that, as part of the changes to the Premium Formulary, Advair HFA and Breo Ellipta were the only covered asthma medications available to Kriete Plan members as of January 1, 2024. Optum Rx denies the remaining allegations in paragraph 23.

24. This practice of requiring patients to change their medications so that PBMs can collect kickbacks from the drug manufacturers is called "non-medical switching" because the choice of medication is dictated by the PBM's financial interests, not the best medical interests of patients.

ANSWER: Optum Rx denies that changes to its formularies are dictated by Optum Rx's "financial interests." Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 24 and therefore denies the same.

25. Under OptumRx's updated 2024 formulary, a patient with a prescription for Advair Diskus, or a generic alternative, could only have that prescription filled if the patient obtained a "Prior Authorization," which required the prescribing physician to specifically ask OptumRx to cover the medication in advance, and for OptumRx to specially approve the medication before the prescription was filled.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor clients. Optum Rx admits that, under the formulary the Kriete Plan chose to adopt effective January 1, 2024, brand Advair Diskus was excluded, and patients required step therapy to obtain coverage for generic fluticasone-salmeterol diskus. Three clinically appropriate

alternatives were offered; one of which, Advair HFA, contained the same active ingredient as the brand Advair Diskus. Optum Rx denies any remaining allegations in paragraph 25.

26. According to OptumRx's Provider Manual, when a Prior Authorization is required, the patient or their physician and/or pharmacist must go through the following steps before the drug can be dispensed:

Prior Authorization (PA) Process Key Steps:

- The Member's Prescriber or Member's appointed/authorized representative can submit a PA request.
- If the request and the provided information falls within established guidelines, the request will be approved.
- If the request and provided information falls outside the established guidelines, a Pharmacist reviews the request and contacts the prescriber if additional information is required.
- If required by state law, the request will be reviewed by a medical director before issuing the final decision.
- Additionally, where required by law, the Prescriber is offered the opportunity for a peer-to-peer consultation prior to the issuance of an adverse medical necessity determination.

Once the request is approved or denied, our PA system will automatically generate a written correspondence to both the Member and Prescriber.

ANSWER: Optum Rx admits that paragraph 26 accurately quotes an excerpt from the 2024 Second Edition Version 2.1 of the Optum Rx Provider Manual. The Provider Manual is the best evidence of its own text and Optum Rx denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 26.

27. Also according to OptumRx's Provider Manual, even "urgent cases have a turnaround time of seventy-two (72) hours for commercial Benefit Plans, from receipt of request to review the case."

ANSWER: Optum Rx admits that paragraph 27 accurately quotes an excerpt from the 2024 Second Edition Version 2.1 of the Optum Rx Provider Manual. The Provider Manual is the best evidence of its own text and Optum Rx denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 27.

28. Similar to the Prior Authorization process is Step Therapy, which requires a patient to first take a "preferred" drug of OptumRx's choosing for a dictated period of time, before they can take the drug prescribed by that patient's doctor.

ANSWER: Optum Rx admits that step therapy promotes the use of one or more safe and cost-effective alternatives prior to authorizing coverage for a requested product. Optum Rx denies any remaining allegations in paragraph 28.

29. In this case, OptumRx required that patients prescribed Advair Diskus undergo Step Therapy and try preferred drugs from manufacturers that had provided kickbacks, such as Advair HFA, Breo Ellipta, or Symbicort first, before they could refill their doctors' prescriptions for Advair Diskus or its generic equivalents.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor clients. Optum Rx admits that, pursuant to the formulary the Kriete Plan chose to adopt effective January 1, 2024, brand Advair Diskus was excluded, and patients required step therapy to obtain coverage for generic fluticasone-salmeterol diskus. Three clinically appropriate alternatives were offered; one of which, Advair HFA, contained the same active ingredient as the brand Advair Diskus. Optum Rx denies that it received kickbacks and denies the remaining allegations in paragraph 29.

30. OptumRx could have structured its formulary to allow existing patients taking Advair Diskus to continue refilling their prescriptions without difficulty, and only require Step Therapy and/or Prior Authorization for new prescriptions of Advair Diskus ("new cases only").

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor clients. Optum Rx admits that it maintains a Continuation of Therapy Policy that provides exceptions to formulary exclusions for certain drugs and certain patients. Advair Diskus did not meet the requirements of the Continuation of Therapy policy because equivalent alternative drugs were available and switching to the available equivalents would not have been medically detrimental to patients. Optum Rx denies any remaining allegations in paragraph 30.

31. OptumRx chose not to do so, because applying the new, non-medical criteria to existing patients would generate far more money in kickbacks to OptumRx.

ANSWER: Optum Rx denies the allegations in paragraph 31.

32. OptumRx also could have left the generic equivalent of Advair Diskus on the formulary, while excluding the brand version of Advair Diskus, but refused to do so because it wanted to drive the patients to other brands like Breo Ellipta, in order to receive the kickbacks from those brand manufacturers.

ANSWER: Optum Rx denies the allegations in paragraph 32. The generic equivalent of Advair Diskus was available on the Kriete Plan formulary subject to a step therapy protocol.

33. Under Wisconsin law, pharmacists have discretion to substitute a brand prescription with its generic equivalent, without prescriber approval, unless otherwise specified in the prescription. A pharmacist, however, cannot substitute one branded prescription for another without prescriber approval.

ANSWER: Paragraph 33 states a legal conclusion to which no response is required.

34. OptumRx also dictates the prices charged for drugs to the pharmacy providers in its network and specifies that failing to charge the price OptumRx dictates, or charging for non-covered ingredients, may subject the pharmacy to termination from OptumRx's network, which would deprive the pharmacy of a significant portion (approximately 20%) of their business.

ANSWER: Optum Rx admits that it negotiates reimbursement terms with participating network pharmacies at arms' length. In accordance with applicable network agreements, when submitting for reimbursement of covered prescription services, network pharmacies are prohibited from charging a member more than the cost sharing amount provided by Optum Rx's point-of-sale system in accordance with the member's benefit plan, including charging for non-covered ingredients. For non-covered prescriptions or services, a member may choose to pay out of pocket, which Optum Rx understands the pharmacy will bill at its usual and customary price charged to the general public at the time of dispensing. Optum Rx denies any remaining allegations in paragraph 34.

35. An OptumRx publication presented the following alternatives to patients who immediately needed a drug that requires a prior authorization:

Getting a short term supply

If you must take a medication that requires prior authorization right away, there are two options that may work for you. First, ask your doctor if a sample is available. Or, check with your pharmacy to request a short-term supply of 5 days or less. Keep in mind, you will be responsible for the full cost at that time. If the prior authorization request is approved, then your pharmacist can fill the rest of your prescription.

If you see your medication listed, we encourage you to talk with your doctor about your treatment and medication options. If you have questions about the PA process, call the phone number on your member ID card.

ANSWER: Optum Rx admits that paragraph 35 accurately quotes an excerpt from its Member Booklet for members of the Kriete Plan as of January 1, 2024. The Member Booklet is the best evidence of its own text and Optum Rx denies any allegations inconsistent with its full text.

36. Neither of these options were viable for patients taking Advair Diskus because first, Advair Diskus was a mature drug which had been on the market for many years, so the manufacturer no

longer made free samples available, and second, Advair Diskus is an inhaler, which is not available in a five-day supply.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 and therefore denies the same. Moreover, the Kriete Plan formulary effective January 1, 2024, included three effective and safe alternatives to Advair Diskus that would not have required prior authorization or step therapy.

37. According to OptumRx's own Provider Manual, Prior Authorizations should only be required for drugs which may not be medically necessary, such as to:

prevent coverage of select products that have potential for use that is typically outside the scope of the pharmacy or medical benefit (e.g., prescribed for treatment of conditions for which there is insufficient clinical evidence supporting safe and/or effective use); use for conditions which are not covered by the Plan (e.g., cosmetic use, or conditions excluded by the Plan); or use in situations where quantity or duration of treatment exceeds those defined as safe and effective in clinical compendia, treatment guidelines or supported through published and/or consulted expert opinion (e.g., OptumRx National P&T Committee).

ANSWER: Optum Rx denies the allegations in paragraph 37.

38. None of these criteria applied to Advair Diskus or its generic equivalents, which are safe and effective for asthma, and fall well within the scope of the pharmacy benefit.

ANSWER: Optum Rx denies that the Kriete Plan formulary effective January 1, 2024, included coverage of Advair Diskus subject to prior authorization; instead, that formulary included multiple safe, therapeutically-equivalent alternatives that provided better overall value for the Kriete Plan and its members. The Kriete Plan formulary also provided coverage for generic fluticasone-salmeterol diskus subject to step therapy. Optum Rx denies any remaining allegations in paragraph 38.

39. Because Prior Authorizations can deprive patients of needed medications, the standard of

care in the PBM industry, and statutory law in many states including Wisconsin, mandates that PBMs advise patients in advance of formulary changes that will adversely affect their ability to access their existing medications, whether that is by increasing the patient's cost or excluding coverage altogether.

ANSWER: Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx admits that Wisconsin law regulates notification of certain formulary changes, but denies that any such regulation applied to Optum Rx as it related to Mr. Schmidtknecht. Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 39 and therefore denies the same.

40. Indeed, OptumRx's own website tells prescribing physicians that:

During formulary cycle updates, OptumRx reaches out to impacted patients with the information they need, including suggested covered alternative medications. We're here to support you and your patients through this process. (emphasis original)

and

Certain states require OptumRx to communicate prior authorization changes before the effective date. Flyers are sent to members to outline the drugs affected by prior authorization, quantity limits, and step therapy based on benefit plan designs. Please review each document for more details.

ANSWER: Optum Rx admits that paragraph 40 accurately quotes an excerpt from its website. The website is the best evidence of its own text and Optum Rx denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 40.

41. One of those "certain states" is Wisconsin, which puts certain restrictions on a PBM's authority to require prior authorization.

ANSWER: Paragraph 41 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states any Wisconsin statute alluded to regarding

regulation of PBMs would be the best evidence of its own text. Optum Rx denies any remaining allegations in paragraph 41.

42. First, Wisconsin law requires at least thirty (30) days advance notice of any formulary change that removes a drug from their formulary or places it on a higher (i.e. more expensive) tier, to give enrollees the chance to request an exception to the formulary change. WIS. STAT. § 632.861(4).

ANSWER: Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states that the referenced statute is the best evidence of its own text and denies Plaintiffs' paraphrasing to the extent inconsistent with the statute's full text, which only requires notice to an enrollee who was using the subject drug at the time notice is due, Wis. Stat. § 632.861(4)(a), and does not require notice where equivalent drugs are available on the formulary at the same tier level as the excluded drug. *Id.*, 632.861(4)(b)(2). Further, notification under Wis. Stat. § 632.861(4) is not the sole obligation of a PBM as the same requirement applies, in the alternative, to a disability insurance policy or self-insured health plan. Optum Rx denies any remaining allegations in paragraph 42.

43. Next, Wisconsin Law requires that any Step Therapy protocol imposed by a PBM like OptumRx be based on "clinical review criteria that are based on clinical practice guidelines that are derived from peer-review publications, evidence-based research, and widely accepted medical practice. If such clinical practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization shall derive clinical review criteria from peer-reviewed publications, evidence-based research, and widely accepted medical practice." WIS. STAT. § 632.866 (2)(a).

ANSWER: Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states that the referenced statute is the best evidence of its own text and denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 43.

44. There is no legitimate peer-reviewed publication or evidence-based research that supports switching a patient whose asthma is well-controlled by Advair Diskus to a different medication.

Optum Rx denies the allegations in paragraph 44. ANSWER:

45. To the contrary, peer reviewed literature establishes that this kind of non-medical switching is associated with adverse medical outcomes.

Optum Rx denies the allegations in paragraph 45. The drugs equivalent to ANSWER: Advair Diskus available on the Kriete Plan formulary as of January 1, 2024, are safe and effective alternatives to Advair Diskus, and Optum Rx is not aware of any study associating switching from Advair Diskus to those drugs with adverse medical outcomes.

The same Wisconsin statute further requires that "[a]n insurer, Pharmacy Benefit Manager, 46. or utilization review organization shall describe on its internet site the process and criteria used for selecting and evaluating clinical practice guidelines [] to develop step therapy protocols." WIS. STAT. § 632.866 (2)(c).

ANSWER: Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states that the referenced statute is the best evidence of its own text and denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 46.

47. In addition to the duties imposed by Wisconsin statutes, PBMs such as OptumRx have a common law duty of managing pharmacy benefits with reasonable care.

Paragraph 47 states a legal conclusion to which no response is required. To ANSWER: the extent a response is required, Optum Rx denies the allegations in paragraph 47.

COLE SCHIMDTKNECHT IS DENIED HIS MEDICATION

48. Twenty-two-year-old Cole Schmidtknecht had a medical history of chronic asthma, stemming from infancy.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 and therefore denies the same.

49. Cole managed his asthma with daily preventative doses of Advair Diskus. Advair Diskus and its generic equivalents had safely and effectively treated Cole's asthma for more than a decade.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 and therefore denies the same. Optum Rx has no record of Mr. Schmidtknecht filling a claim for Advair Diskus pursuant to an Optum Rx-administered plan since April 5, 2022, when a claim for a 30-day supply of Advair Diskus was filled for a copay amount of \$60.

50. In 2023, Cole began working for Kriete Truck Center Green Bay [hereinafter "Kriete Trucking"], located at 2090 Mid Valley Drive, De Pere, Wisconsin 54115, where he earned a modest hourly wage.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 and therefore denies the same.

51. In August of 2023, Cole switched from his parent's plan to a Kriete Trucking's fully insured plan that was administered by United Health. Under this plan, OptumRx was the PBM for Cole's prescription medications.

ANSWER: On information and belief, Optum Rx admits that Mr. Schmidtknecht was a beneficiary under a fully-insured UnitedHealthcare plan sponsored by Kriete Group for various dates in 2022 and 2023, ending January 31, 2023, and thereafter, Mr. Schmidtknecht became a

member under the same fully-insured plan in or about July of 2023. Optum Rx further admits that Optum Rx was the PBM for the Kriete Plan during these time periods.

52. Cole's prescription for Advair Diskus had historically been covered by his insurance. Under the United Health-OptumRx plan in 2023, Cole's asthma medication, Advair Diskus, was covered and would cost no more than about \$66.86, even during the deductible phase of coverage, or about \$35 during the covered phase.

ANSWER: Optum Rx admits that brand Advair Diskus was covered under certain previous versions of the formulary that the fully-insured UnitedHealthcare plan sponsored by Kriete Group had adopted at that time. Optum Rx admits that brand Advair Diskus was available to at least one member of the fully-insured Kriete Plan at a different pharmacy on a particular date in 2023 at a cost of \$66.86 for a thirty-day supply. Optum Rx denies that Mr. Schmidtknecht submitted any claims whatsoever in 2023 for Advair Diskus using his Optum Rx-administered benefit under the fully-insured Kriete Plan. Optum Rx denies the remaining allegations in paragraph 52.

53. As of January 1, 2024, the Kriete Trucking plan became a self-insured plan administered by UMR, a United Health subsidiary, with OptumRx remaining as the PBM.

ANSWER: Optum Rx admits that UMR, Inc. is a subsidiary of UnitedHealth Group Incorporated and operates as a third-party administrator, helping group health plans administer health care benefits for their members. UMR administered the self-insured Kriete Plan beginning January 1, 2024, and Optum Rx served as the PBM for the Kriete Plan in January 2024.

54. On January 10, 2024, Cole went to his local Walgreens Pharmacy, Store # 12693, located at 729 West Northland Avenue, Appleton, Wisconsin 54914, expecting to fill his usual prescription for his Advair Diskus inhaler, as prescribed by his physician.

ANSWER: Optum Rx admits that, on or about January 10, 2024, Optum Rx's records reflect that Walgreens submitted to Optum Rx a claim in Mr. Schmidtknecht's name for a 180-day supply of Advair Diskus. Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 54 and therefore denies the same.

55. At the pharmacy, Cole was advised by an employee of the Walgreens Defendants that his medication was no longer covered by his insurance and that his Advair Diskus preventative inhaler would cost him \$539.19 out of pocket.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 and therefore denies the same.

56. By November 2023 at the latest, and upon information and belief at an earlier date, OptumRx had already determined that Advair Diskus and its generic equivalents would not be covered by the formularies starting in 2024.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor customers. Optum Rx admits that, in September 2023, the Optum Rx P&T Committee, in conducting its review of respiratory products used to treat asthma and chronic obstructive pulmonary disease, recommended that with the generic availability of fluticasone-salmeterol diskus, as well as other changes in the market, that therapeutic class on Optum Rx 2024 standard formularies would exclude brand Advair Diskus and add three inhalers as preferred alternatives: Advair HFA, Breo Ellipta, and Symbicort, all of which are clinically appropriate, safe and effective alternatives and have the same clinical profile as brand Advair Diskus (and, in the case of Advair HFA, has the same active ingredients). Further answering, Optum Rx states that generic fluticasone-salmeterol diskus was covered as a Tier 1 (lowest copay) drug subject to step therapy. Optum Rx denies any remaining allegations in paragraph 56.

57. Likewise, by November 2023 at the latest, and upon information and belief at an earlier date, OptumRx had already determined that they would be requiring patients to undergo mandatory step therapy prior to receiving Advair Diskus or its generic equivalents starting in 2024.

Optum Rx denies that it dictates prescription drug coverage decisions for its ANSWER: plan sponsor customers. Optum Rx admits that, in September 2023, it adopted the recommendation of its P&T Committee to exclude Advair Diskus from certain of its standard formularies. Further answering, Optum Rx states that in conducting its review of respiratory products used to treat asthma and chronic obstructive pulmonary disease, the Optum Rx P&T Committee determined that with the generic availability of fluticasone-salmeterol diskus, as well as other changes in the market, that therapeutic class on Optum Rx 2024 standard formularies would add three inhalers as preferred alternatives: Advair HFA, Breo Ellipta, and Symbicort, all of which are clinically appropriate, safe and effective alternatives and have the same clinical profile as brand Advair Diskus (and, in the case of Advair HFA, has the same active ingredients). Further answering, Optum Rx states generic fluticasone-salmeterol diskus was covered as a Tier 1 (lowest copay) drug subject to step therapy Optum Rx denies any remaining allegations in paragraph 57.

58. And yet, despite the clear requirement under Wisconsin law, and the common law standard of care for PBMs, OptumRx never provided Cole with thirty (30) days' notice, or any advance notice whatsoever, that neither his Advair Diskus, nor its generic equivalents, would not be covered by his insurance in 2024.

ANSWER: Paragraph 58 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies that Mr. Schmidtknecht was not sent advance notice of changes to the Kriete Plan formulary, including the exclusion of brand Advair Diskus. Optum Rx denies that Mr. Schmidtknecht was entitled under Wisconsin law to thirty days' notice of the exclusion of Advair Diskus because, among other reasons, Optum Rx has no record of Mr. Schmidtknecht filling a claim for Advair Diskus pursuant to an Optum Rx-administered plan since April 5, 2022. Optum Rx denies the remaining allegations of paragraph 58.

59. OptumRx did not provide this notice to Cole at any time in the year prior to January 10, 2024, despite the fact that Cole had been on two plans with OptumRx acting as the PBM beforehand.

ANSWER: Optum Rx denies that Mr. Schmidtknecht was not sent advance notice of changes to the Kriete Plan formulary, including the exclusion of brand Advair Diskus. Optum Rx denies that Mr. Schmidtknecht was entitled under Wisconsin law to thirty days' notice of the exclusion of Advair Diskus because, among other reasons, Optum Rx has no record of Mr. Schmidtknecht filling a claim for Advair Diskus pursuant to an Optum Rx-administered plan since April 5, 2022. Optum Rx denies the remaining allegations of paragraph 59.

60. Likewise, OptumRx did not provide Cole with notice of any global changes to the formulary under either of their plans at any point in the year prior to January 10, 2024.

ANSWER: Optum Rx denies the allegations in paragraph 60.

61. Under Wisconsin law, the common law standard of care, and according to OptumRx's own policies and procedures, this change should have been communicated to Cole and similarly situated patients, by or before December 1, 2023, at the latest.

ANSWER: Paragraph 61 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 61.

62. As a result of this lack of notice, Cole did not have the opportunity to ask for an exception to OptumRx's re-classification of the medication under its formulary that suddenly made his normal medication prohibitively expensive.

ANSWER: Optum Rx denies the allegations in paragraph 62.

63. Also contrary to requirements under Wisconsin law, OptumRx did not describe its process and criteria for selecting and evaluating step therapy protocols on the internet before requiring Cole to switch medications for no medical reason.

ANSWER: Optum Rx denies the allegations in paragraph 63.

64. According to a statement by OptumRx, in this scenario, the Walgreens pharmacist should have contacted Cole's prescribing physician about three other "clinically-appropriate alternatives available at a Tier-1 [more affordable] Co-pay: "Premium Drug Exclusion: Drug Not Covered; - Contact prescriber; Use Advair HFA; Breo Ellipta; Symbicort."

ANSWER: Optum Rx admits that the quoted statement in paragraph 64 was transmitted to Walgreens by Optum Rx's electronic claims adjudication system in response to a claim for Advair Diskus for Mr. Schmidtknecht that Walgreens submitted through that system on January 10, 2024. Optum Rx denies any allegations inconsistent with the full text of the referenced message and denies any remaining allegations in paragraph 64.

65. Walgreens Defendants did not follow these instructions.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65 and therefore denies the same.

66. Walgreens Defendants never provided Cole with any more affordable workarounds to obtain his usual inhaler for his chronic asthma.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66 and therefore denies the same.

Walgreens Defendants did not offer Cole a generic alternative to Advair Diskus and further told Cole that there were no cheaper alternatives or generic medications available.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67 and therefore denies the same.

68. Walgreens Defendants did not contact OptumRx to request an exception to the reclassification on Cole's behalf.

ANSWER: Optum Rx admits that Walgreens did not request that Optum Rx provide an exception to the exclusion of Advair Diskus as a covered drug under the Kriete Plan in connection with Mr. Schmidtknecht's January 10, 2024 prescription fill request for Advair Diskus.

69. Likewise, Walgreens Defendants did not contact Cole's prescribing physician to ask them to request an exception on Cole's behalf.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 and therefore denies the same.

70. Walgreens Defendants did not provide Cole with a free or discounted Advair Diskus inhaler for him to use until he was able to contact his physician or United Health.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 and therefore denies the same.

71. In fact, Walgreens Defendants did not take any steps to attempt to help Cole obtain the medication that he relied upon to control his asthma.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 and therefore denies the same.

72. Because Cole could not afford this unexpected expense of \$539.19, he left the Walgreens without filling his prescription.

ANSWER: Optum Rx admits only that Mr. Schmidtknecht's prescription for a 180-day supply of Advair Diskus adjudicated on or about January 10, 2024, was not filled. On information and belief, Mr. Schmidtknecht did fill a prescription for albuterol at that time. Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 72 and therefore denies the same.

73. By removing Advair Diskus and its generic equivalents from its formulary, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.

ANSWER: Optum Rx denies the allegations in paragraph 73.

74. By removing Advair Diskus and its generic equivalents from its formulary without giving Cole thirty days' notice or any other reasonable advance notice to request an exception, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.

ANSWER: Optum Rx denies the allegations in paragraph 74.

75. By requiring a Prior Authorization for the prescription for Advair Diskus and its generic equivalents, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.

ANSWER: Optum Rx denies the allegations in paragraph 75.

76. By requiring Cole to undergo a step-up regimen before he could fill his prescription for Advair Diskus and its generic equivalents, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.

ANSWER: Optum Rx denies the allegations in paragraph 76.

77. OptumRx knew or should have known that Cole would be forced to leave the Walgreens pharmacy without his life-sustaining medication.

ANSWER: Optum Rx denies the allegations in paragraph 77.

78. Over the next five days, Cole repeatedly struggled to breathe, relying solely on his old "rescue" (emergency) inhaler to limit his symptoms, because he did not have a preventative inhaler designed for daily use.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 and therefore denies the same.

79. On January 15, 2024, five days after visiting the OptumRx-Walgreens pharmacy, Cole had a severe asthma attack and began to asphyxiate.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 and therefore denies the same.

80. His roommate, Mitchell Huiting, immediately drove him to the Emergency Room at ThedaCare Regional Medical Center-Appleton, located at 1818 North Meade Street, Appleton, Wisconsin 54911.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 80 and therefore denies the same.

81. Cole became unresponsive and pulseless in the car, about two minutes before they arrived.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 81 and therefore denies the same.

82. When he presented to the ER, practitioners recorded that Cole was unconscious, pulseless, and appeared blue.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 and therefore denies the same.

83. Emergency medical staff immediately gave Cole two rounds of epinephrin and performed two rounds of Cardiopulmonary Resuscitation, lasting over four minutes, to try to get him to regain consciousness.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 and therefore denies the same.

84. Despite their best efforts, Cole never woke up again.

Optum Rx lacks knowledge or information sufficient to form a belief as to ANSWER: the truth of the allegations in paragraph 84 and therefore denies the same.

85. Cole remained in the Intensive Care Unit on a ventilator for six days, until doctors finally informed his parents, William and Shanon Schmidtknecht, that he was beyond help.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 and therefore denies the same.

86. On January 21, 2024, Cole's parents agreed to withdraw life supporting care and Cole was pronounced dead.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 and therefore denies the same.

87. The immediate cause of death listed on his death certificate was status asthmaticus.

Optum Rx lacks knowledge or information sufficient to form a belief as to ANSWER: the truth of the allegations in paragraph 87 and therefore denies the same.

88. As a result of these events, Cole suffered the following injuries and damages:

- Severe asthma attack; a.
- b. Asphyxiation;
- c. Shortness of breath;
- d. Traumatic brain injury;
- Altered level of consciousness; e.
- f. Starvation of oxygen;
- Hypoxia; g.
- h. Hypothermia;
- i. Panic;
- j. Pain and suffering;
- k. **Emotional distress:**
- 1. Mental anguish;
- Loss of life's pleasures; m.
- Loss of earnings; and n.
- Death 0.

Optum Rx lacks knowledge or information sufficient to form a belief as to ANSWER: the truth of the allegations in paragraph 88 and therefore denies the same.

- As a result of Cole Schmidtknecht's death, Plaintiffs Shanon Schmidtknecht, and William Schmidtknecht, and the Estate of Cole Schmidtknecht suffered the following damages:
 - lost earnings of Cole Schmidtknecht between the time of his injury and his death; a.
 - b. Cole Schmidtknecht's total estimated future earning power less his cost of personal maintenance;
 - pain and suffering endured by Cole Schmidtknecht prior to his death, including, but c. not limited to, physical pain and suffering, mental pain and suffering, mental suffering, loss of life's pleasures, disfigurement, and humiliation;
 - d. medical expenses;

- funeral, and burial expenses; e.
- f. monetary support Cole Schmidtknecht would have provided during his lifetime, the value of services provided or which could have been expected to have been performed in the future by Cole Schmidtknecht, and all pecuniary losses suffered as a result of Cole Schmidtknecht's death;
- Individual plaintiffs Shanon Schmidtknecht and William Schmidtknecht lost the g. society and companionship of their son, Cole Schmidtknecht;
- other serious and severe injuries, the exact nature of which are unknown to Plaintiff h. at this time; and
- i. all damages available under Wisconsin law.

ANSWER: Optum Rx lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 89 and therefore denies the same.

COUNT I: NEGLIGENCE

Plaintiffs v. Defendant OptumRx

90. The preceding paragraphs are incorporated by reference as though fully set forth herein.

ANSWER: Optum Rx incorporates its responses to each of the preceding paragraphs as though set forth fully herein.

At all relevant times, Defendant OptumRx engaged in the business of providing and managing the pharmacy benefits to millions of people, including Cole Schmidtknecht.

ANSWER: Optum Rx admits that it is a pharmacy benefits manager and that, pursuant to its contract with UMR, Inc., a third-party administrator which administered the self-insured Kriete Plan beginning January 1, 2024, Optum Rx served as the PBM for the Kriete Plan under which Mr. Schmidtknecht was covered. On information and belief, Optum Rx admits that prior to January 1, 2024, Mr. Schmidtknecht was a beneficiary under a fully-insured UnitedHealthcare plan sponsored by Kriete Group for various dates in 2022 and 2023, ending January 31, 2023, and

thereafter, Mr. Schmidtknecht became a member under the same fully-insured plan in or about July of 2023. Optum Rx further admits that Optum Rx was the PBM for the Kriete Plan during these time periods. Optum Rx denies that it provides pharmacy benefits to plan members and denies the remaining allegations of paragraph 91.

92. Defendant OptumRx had a duty to not artificially inflate prescription drug prices for medications such as Advair Diskus for insured patients, including Cole Schmidtknecht, making them so unaffordable that patients could not obtain the medications their physicians prescribed.

ANSWER: Paragraph 92 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 92.

93. Defendant OptumRx had a duty to inform asthmatic patients, including Cole Schmidtknecht, who were previously taking and who had been continuously prescribed Advair Diskus, of their decision to reschedule the medication and the impact this decision would have on pricing, so patients could request an exception to the rescheduling by the PBM.

ANSWER: Paragraph 93 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 93.

- 94. Defendant OptumRx failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm resulting from:
 - a. Failing to ensure that asthma patients, including Cole Schmidtknecht, had access to Advair Diskus, or its generic equivalent, as prescribed by their physician;
 - b. Failing to notify Cole Schmidtknecht that the medication that he had been relying on for years would be dramatically increasing in price;
 - c. [sic]
 - d. Failing to give at least thirty (30) days advance notice to asthmatic patients, including Cole Schmidtknecht, that the medication that he had been relying on for years would no longer be covered, so that they could request an exception before their next refill;
 - e. Failing to afford an exception to Cole Schmidtknecht to OptumRx's re-scheduling

- of Advair Diskus to a not covered drug, despite his long history of taking, relying on, and benefitting from Advair Diskus without any negative side effects;
- f. Forcing patients, including Cole Schmidtknecht, who had historically taken Advair Diskus to switch to another asthma medication for no sound medical reason, in violation of the standards expressed in OptumRx's own Provider Manual; See, e.g., para. 43 supra.
- Forcing patients, including Cole Schmidtknecht, who had historically taken Advair g. Diskus to adhere to a step-up regimen on another medication for no sound medical reason and without supporting peer-reviewed medical literature;
- h. Failing to provide retail pharmacies, including Walgreens, with information to provide to patients who were impacted by their rescheduling of Advair Diskus to a not covered drug, so that they could obtain an alternative medication, such as a generic substitute;
- i. Requiring and/or approving Walgreens charge of \$539 to fill Cole's Advair Diskus prescription;
- j. Failing to provide the Walgreens pharmacy located at 729 West Northland Avenue, Appleton, with information and/or means necessary to make sure that patients, including Cole Schmidtknecht, who were adversely impacted by the formulary change, would receive a covered alternative medication before these patients left the pharmacy; and
- k. Failing to provide employees at the Walgreens pharmacy located at 729 West Northland Avenue, Appleton, Wisconsin 54914 with information to provide Cole Schmidtknecht with regarding the impacts of the re-scheduling of Advair Diskus to a not covered drug, so that he could obtain an alternative medication.

Paragraph 94 states a legal conclusion to which no response is required. To **ANSWER:** the extent a response is required, Optum Rx denies the allegations in paragraph 94.

95. Defendant OptumRx failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm to asthmatic patients, including Cole Schmidtknecht, which would result from their failing to provide access to Advair Diskus or its generic alternatives without sufficient advance notice.

ANSWER: Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 95.

96. As a direct and proximate result of the acts and omissions of Defendant OptumRx, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries described above.

ANSWER: Optum Rx denies the allegations in paragraph 96.

97. The negligence of Defendant OptumRx and its employees, agents, ostensible agents, shareholders, officers, directors, and/or managing agents, as set forth above, was a direct and proximate cause of the injuries and damages suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht.

ANSWER: Optum Rx denies the allegations in paragraph 97.

WHEREFORE, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, respectfully demand judgment against Defendants, jointly and severally, for sums in excess of local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

ANSWER: Optum Rx denies that Plaintiffs are entitled to judgment in their favor, to the relief requested or to any relief at all in this action.

COUNT II: NEGLIGENCE

Plaintiffs v. Walgreens Defendants

98. The preceding paragraphs are incorporated by reference as though fully set forth herein.

ANSWER: Optum Rx incorporates its responses to each of the preceding paragraphs as though set forth fully herein.

99. At all relevant times, Walgreens Defendants engaged in the business of providing prescription medications to pharmacy patients.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 99.

100. Walgreens Defendants had a duty to provide medications such as Advair Diskus to patients, including Cole Schmidtknecht, as their physicians prescribed, or if their prescribed medication was not covered by their health insurance, exercise reasonable care to provide affordable alternative options to patients, including Cole Schmidtknecht, at the point of service.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 100.

101. Walgreens Defendants had a duty to inform asthmatic patients who were previously taking and had been continuously prescribed Advair Diskus, including Cole Schmidtknecht, of OptumRx's decision to reschedule the medication and the impact this decision had on pricing, and work to find alternative ways for patients, including Cole Schmidtknecht, to fill their prescriptions.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 101.

- 102. Walgreens Defendants failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm resulting from:
 - a. Failing to seek OptumRx's approval to fill the prescription;
 - b. Failing to seek OptumRx's approval to fill the prescription with the generic equivalent;
 - c. Failing to immediately request a Prior Authorization from OptumRx on an urgent basis;
 - d. Failing to immediately contact Cole's prescribing physician to request a new prescription to a covered medication on an urgent basis;
 - e. Failing to immediately contact Cole's prescribing physician so they could immediately request a Prior Authorization from OptumRx on an urgent basis;
 - f. Failing to provide an emergency supply of Advair Diskus or its generic equivalent to Cole Schmidtknecht;

- g. Failing to provide an emergency supply of one of the covered asthma medications to Cole Schmidtknecht for him to rely on while the Prior Authorization was pending;
- h. Failing to inform Cole that these requests had been made and that his medication would become available to him at an affordable price in 72 hours;
- i. Failing to adequately train staff around how to perform services to ensure patients were advised of all the options open to them and received necessary pharmacy services;
- j. Failing to provide adequate staffing and resources to its retail pharmacy locations to ensure patients were advised of all the options open to them and received necessary pharmacy services; and
- k. Failing to take corrective actions to ensure patients received necessary medical services and were advised of all the options open to them following multiple indications that pharmacists were under-trained, and pharmacies were under-staffed and under- resourced, and therefore could not ensure patients received necessary pharmacy services and were advised of all the options open to them.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 102.

103. Instead of taking any of these steps, Walgreens Defendants simply told Cole that his medication would cost \$539.19.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 103.

104. The price was unconscionably high, and well above Walgreens Defendants' acquisition cost for this drug.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 104.

105. Walgreens Defendants had a duty to notify asthmatic patients, including Cole Schmidtknecht, who were previously taking and had been continuously prescribed Advair Diskus, of OptumRx's decision to reschedule the medication and the impact this decision had on pricing, and work to find alternative ways for patients, including Cole Schmidtknecht, to fill their prescriptions.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 105.

106. Walgreens Defendants failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risk of harm to asthmatic patients, including Cole Schmidtknecht, that would result from their failing to provide him with Advair Diskus or a medically equivalent alternative medication at an affordable price at the point of service.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 106.

107. As a direct and proximate result of the acts and omissions of Walgreens Defendants, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries and damages as set forth above.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 107.

108. The negligence of Walgreens Defendants and its employees, agents, ostensible agents, shareholders, officers, directors, and/or managing agents, as set forth above, was a direct and proximate cause of the injuries and damages suffered by Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies the allegations in paragraph 108.

WHEREFORE, Plaintiffs Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgement interest, and costs.

ANSWER: Count II is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count II. To the extent a response is required, Optum Rx denies that Plaintiffs are entitled to judgment in their favor, to the relief requested, or to any relief at all in this action.

COUNT III: NEGLIGENCE PER SE VIOLATION OF THREE WISCONSIN STATUTES ESTABLISHING A STANDARD OF CARE FOR PBMS

Plaintiffs v. Defendant OptumRx

109. The preceding paragraphs are incorporated by reference as though fully set forth herein.

ANSWER: Optum Rx incorporates its responses to each of the preceding paragraphs as though set forth fully herein.

At all relevant times, Cole Schmidtknecht was an enrollee as defined by WIS. STAT. § 632.861(1)(b).

Optum Rx denies the allegations in paragraph 110. ANSWER:

Defendant OptumRx's treatment of Cole Schmidtknecht violated three different Wisconsin statutes: WIS. STAT. § 632.861(3), WIS. STAT. § 632.861(4) and WIS. STAT. § 632.866 (2)(a).

Optum Rx denies the allegations in paragraph 111. ANSWER:

- Under WIS. STAT. § 632.861(3), a PBM shall "not require an enrollee to pay at the point of sale for a covered prescription drug an amount that is greater than the lowest of all of the following amounts:
 - (a) The cost-sharing amount for the prescription drug for the enrollee under the policy or plan.
 - (b) The amount a person would pay for the prescription drug if the enrollee purchased the prescription drug at the dispensing pharmacy without using any health plan or health insurance coverage.

WIS. STAT. § 632.861(3)

ANSWER: The referenced statute is the best evidence of its own text, and Optum Rx denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 112.

113. Defendant OptumRx required Cole Schmidtknecht to pay \$539.19 at the point of sale for Advair Diskus.

ANSWER: Optum Rx denies the allegations in paragraph 113.

The \$539.19 for Advair Diskus is an amount greater than the lowest amount of both the cost-sharing amount under the policy/plan and the amount that a person would pay if the enrollee purchased the Advair Diskus at the dispensing pharmacy without using any health plan or health insurance coverage, in violation of Section 632.861(1)(b).

ANSWER: Paragraph 114 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 114.

Wisconsin law also requires at least thirty (30) days advance notice of any formulary change that removes a drug from the formulary or places it on a higher (more expensive) tier, and simultaneously inform the enrollees like Cole of the procedure for the enrollee to request an exception to the formulary change. WIS. STAT. § 632.861(4).

ANSWER: Paragraph 115 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states that the referenced statute is the best evidence of its own text and denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 115.

116. On January 1, 2024, Defendant OptumRx changed Advair Diskus from a covered drug to an excluded drug that would only be covered if the patient obtained Prior Authorization or went through step therapy.

ANSWER: Optum Rx denies that it dictates prescription drug coverage decisions for its plan sponsor customers. Optum Rx admits that the formulary adopted by the Kriete Plan, effective January 1, 2024, excluded brand Advair Diskus as a covered medication, while offering three clinically appropriate, safe and effective therapeutically-equivalent alternatives to Advair Diskus that would not have required prior authorization or step therapy. Optum Rx denies any remaining allegations in paragraph 116.

117. Defendant OptumRx failed to provide Cole Schmidtknecht with thirty (30) days' advanced written notice of the formulary change that removed Advair Diskus from the formulary policy/plan or that reassigned Advair Diskus to a benefit tier for the policy or plan that has a higher deductible, copayment, or coinsurance.

ANSWER: Optum Rx denies that Mr. Schmidtknecht was not sent advance notice of changes to the Kriete Plan formulary, including the exclusion of brand Advair Diskus. Optum Rx denies that Mr. Schmidtknecht was entitled under Wisconsin law to thirty days' notice of the exclusion of Advair Diskus because, among other reasons, Optum Rx has no record of Mr. Schmidtknecht filling a claim for Advair Diskus pursuant to an Optum Rx-administered plan after April 5, 2022. Optum Rx denies any remaining allegations in paragraph 117.

118. Defendant OptumRx did not provide Cole Schmidtknecht with information on the procedure to request an exception to the Advair Diskus formulary change.

ANSWER: Optum Rx denies the allegations in paragraph 118.

119. At all relevant times, Cole Schmidtknecht was using Advair Diskus when thirty (30) days' advanced written notice was required.

ANSWER: Optum Rx denies that Mr. Schmidtknecht filled a claim for Advair Diskus under an Optum Rx-administered plan after April 5, 2022. On information and belief, Optum Rx denies any remaining allegations in paragraph 119.

120. Wisconsin Law also required that any step therapy protocol Defendant OptumRx imposed be based on "clinical review criteria that are based on clinical practice guidelines that are derived from peer-review publications, evidence-based research, and widely accepted medical practice. If such clinical practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization shall derive clinical review criteria from peer-reviewed publications, evidence-based research, and widely accepted medical practice." WIS. STAT. § 632.866 (2)(a).

ANSWER: Paragraph 120 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx states that the referenced statute is the best evidence of its own text and denies any allegations inconsistent with its full text. Optum Rx denies any remaining allegations in paragraph 120.

121. At all relevant times, Defendant OptumRx failed to use clinical review criteria based on clinical practice guidelines derived from peer-review publications, evidence-based research, or widely accepted medical practice when it established its step therapy protocol for Advair Diskus.

ANSWER: Optum Rx denies the allegations in paragraph 121.

122. At all relevant times, Defendant OptumRx failed to continually update the clinical review criteria based on an update to the clinical practice guidelines or a review of new evidence and research and newly developed treatments.

ANSWER: Optum Rx denies the allegations in paragraph 122.

123. Defendant OptumRx had an obligation not to violate State law in providing prescription medications to Plaintiffs' decedent, Cole Schmidtknecht.

ANSWER: Optum Rx admits only that it is required to comply with applicable, non-preempted State law. Optum Rx denies any remaining allegations in paragraph 123.

124. Defendant OptumRx failed to comply with State law in managing pharmacy benefits for Plaintiffs' decedent, Cole Schmidtknecht, including, but not limited to, WIS. STAT. §§ 632.861(3) -(4) and 632.866(2).

ANSWER: Optum Rx denies the allegations in paragraph 124.

125. WIS. STAT. §§ 632.861(3)-(4) and 632.866(2) are safety statutes enacted to protect patients taking prescription drugs.

ANSWER: Paragraph 125 states a legal conclusion to which no response is required. To the extent a response is required, Optum Rx denies the allegations in paragraph 125.

126. Cole Schmidtknecht was in the class that WIS. STAT. §§ 632.861(3)-(4) and 632.866(2) were enacted to protect.

ANSWER: Paragraph 126 states a legal conclusion to which no response is required.

To the extent a response is required, Optum Rx denies the allegations in paragraph 126.

127. The legislative intent in passing WIS. STAT. §§ 632.861(3) -(4) and 632.866(2) as part of the 2021 Wisconsin Act was to protect consumers and increase transparency and accountability in prescription drug pricing.

ANSWER: Optum Rx denies the allegations in paragraph 127.

128. As a direct and proximate result of the acts and omissions of Defendant OptumRx,

Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries and damages as set forth above.

ANSWER: Optum Rx denies the allegations in paragraph 128.

WHEREFORE, Plaintiffs Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgement interest, and costs.

ANSWER: Optum Rx denies that Plaintiffs are entitled to judgment in their favor, to the relief requested, or to any relief at all in this action.

COUNT IV: PUNITIVE DAMAGES

Plaintiffs v. Defendant OptumRx

129. The preceding paragraphs are incorporated by reference as though fully set forth herein.

ANSWER: Optum Rx incorporates its responses to each of the preceding paragraphs as though set forth fully herein.

130. OptumRx intentionally disregarded the rights of Plaintiffs' decedent, Cole Schmidtknecht, and similarly situated individuals when it violated State laws.

ANSWER: Optum Rx denies the allegations in paragraph 130.

131. OptumRx was aware that the result or consequence of serious injury or death was substantially certain to occur when it violated State law and acted in intentional disregard of that serious injury or death.

ANSWER: Optum Rx denies the allegations in paragraph 131.

132. At all relevant times, OptumRx's conduct was grievous and outrageous, and evinced such a degree of intentional disregard of the rights of Cole Schmidtknecht and similarly situated individuals as to warrant punitive damages.

ANSWER: Optum Rx denies the allegations in paragraph 132.

133. OptumRx's grievous and outrageous conduct caused the harms and injuries suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, as set forth above, warranting punitive damages.

ANSWER: Optum Rx denies the allegations in paragraph 133.

COUNT V: PUNITIVE DAMAGES

Plaintiffs v. Walgreens Defendants

134. The preceding paragraphs are incorporated by reference as though fully set forth herein.

ANSWER: Optum Rx incorporates its responses to each of the preceding paragraphs as though set forth fully herein.

135. Walgreens Defendants intentionally disregarded the rights of Plaintiffs' decedent, Cole Schmidtknecht, and similarly situated individuals when it violated State laws.

ANSWER: Count V is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count V. To the extent a response is required, Optum Rx denies the allegations in paragraph 135.

136. Walgreens Defendants were aware that the result or consequence of serious injury or death was substantially certain to occur when they violated State law and acted in intentional disregard of that serious injury or death.

ANSWER: Count V is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count V. To the extent a response is required, Optum Rx denies the allegations in paragraph 136.

137. At all relevant times, Walgreens Defendants' conduct was grievous and outrageous, and

evinced such a degree of intentional disregard of the rights of Cole Schmidtknecht and similarly situated individuals as to warrant punitive damages.

Count V is not directed to Optum Rx, and therefore, Optum Rx need not ANSWER: answer the allegations in Count V. To the extent a response is required, Optum Rx denies the allegations in paragraph 137.

Walgreens Defendants' grievous and outrageous conduct caused the harms and injuries suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, as set forth above, warranting punitive damages.

ANSWER: Count V is not directed to Optum Rx, and therefore, Optum Rx need not answer the allegations in Count V. To the extent a response is required, Optum Rx denies the allegations in paragraph 138.

FIRST CAUSE OF ACTION: WRONGFUL DEATH ACTION

Plaintiffs Shanon Schmidtknecht and William Schmidtknecht individually v. All Defendants

139. The preceding paragraphs are incorporated by reference as though fully set forth herein.

Optum Rx incorporates its responses to each of the preceding paragraphs as ANSWER: though set forth fully herein.

Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually, bring this action under and by virtue of WIS. STAT. § 895.04.

Paragraph 140 calls for a legal conclusion to which no response is required. ANSWER: To the extent a response is required, Optum Rx admits that Shanon Schmidtknecht and William Schmidtknecht purport to bring a cause of action pursuant to Wis. Stat. § 895.04 but denies any remaining allegations in paragraph 140.

141. As a result of the acts and omissions of all Defendants, Cole Schmidtknecht died on January 21, 2024.

Optum Rx denies the allegations in paragraph 141. **ANSWER:**

As a result of the acts and omissions of all Defendants, Plaintiffs, Shanon Schmidtknecht, 142. individually, and William Schmidtknecht, individually, suffered harms and losses which are compensable pursuant to WIS. STAT. § 895.04.

ANSWER: Optum Rx denies the allegations in paragraph 142.

WHEREFORE, Plaintiffs Shanon Schmidtknecht, individually, and William Schmidtknecht, individually, demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgement interest, and costs.

Optum Rx denies that Plaintiffs are entitled to judgment in their favor, to ANSWER: the relief requested, or to any relief at all in this action.

SECOND CAUSE OF ACTION: CLAIM OF THE ESTATE OF COLE **SCHMIDTKNECHT**

Plaintiffs v. All Defendants

143. The preceding paragraphs are incorporated by reference as though fully set forth herein.

Optum Rx incorporates its responses to each of the preceding paragraphs as ANSWER: though set forth fully herein.

144. Cole Schmidtknecht died on January 21, 2024.

Upon information and belief, Optum Rx admits the allegations in paragraph ANSWER: 144.

145. As a result of the acts and omissions of all Defendants, Cole Schmidtknecht was caused grave injuries and death resulting in the entitlement to damages by the Estate of Cole Schmidtknecht, deceased.

ANSWER: Optum Rx denies the allegations in paragraph 145.

146. Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually and as Special Administrator of the Estate of Cole Schmidtknecht, bring this action on behalf of the Estate of Cole Schmidtknecht, deceased, and claims the full measure of damages compensable under Wisconsin law.

ANSWER: Optum Rx admits only that Shanon Schmidtknecht individually and William Schmidtknecht individually as Special Administrator of the Estate of Cole Schmidtknecht purport to bring this action on behalf of the Estate of Cole Schmidtknecht. Optum Rx denies any remaining allegations in paragraph 146.

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

ANSWER: Optum Rx denies that Plaintiffs are entitled to judgment in their favor, to the relief requested, or to any relief at all in this action.

DEFENSES

Without admitting any allegations in Plaintiffs' Amended Civil Action Complaint, Optum Rx asserts and alleges the following defenses. By alleging the defenses now, Optum Rx does not in any way agree or concede that Plaintiffs have properly stated a cause of action in their Amended Civil Action Complaint or that Optum Rx bears the burden of proof or persuasion with respect to any of its defenses. Optum Rx reserves the right to amend these defenses, or to add additional defenses, based upon legal theories, facts, and circumstances that may or will be discovered and/or further legal analysis of Plaintiffs' positions in this litigation.

- 1. Plaintiffs' claims, legal theories, and requested remedies are preempted in their entirety by the Employee Retirement Income Security Act ("ERISA"). Plaintiff's damages, if any, are limited to those damages recoverable under 29 U.S.C. § 1132.
- 2. Plaintiffs cannot state a claim for negligence because Optum Rx did not owe or assume any duty to Mr. Schmidtknecht or any other Plaintiff.
- 3. Plaintiffs' alleged damages were caused by Plaintiffs' and/or Mr. Schmidtknecht's own negligent acts or omissions, and Plaintiffs' recovery, if any, shall be reduced or barred by their comparative negligence.
- 4. Plaintiffs cannot state a claim for negligence per se because they cannot show that Optum Rx violated a safety statute.
- 5. Plaintiffs' claims are barred because they arise under state statutes which do not provide private rights of action, causes of action, or the relief Plaintiffs seek.
- 6. Plaintiffs' claims are barred because Optum Rx was in compliance with all applicable statutes, regulations, or other laws in effect at the time of the alleged conduct.
- 7. Plaintiffs' request for punitive damages violates Optum Rx's due process rights under the United States Constitution, the Fifth and Fourteenth Amendments, and/or the prohibition on "excessive fines" of the United States Constitution, the Eighth Amendment.
- 8. Plaintiffs' claims are barred because any harm allegedly suffered by Plaintiffs or by Mr. Schmidtknecht was not caused by an act or omission of Optum Rx.
- 9. Plaintiffs' claims are or may be barred, in whole or in part, by the applicable statutes of limitations, doctrines of estoppel, waiver, laches, or release, or are otherwise time barred.
- 10. Plaintiffs' claims are barred, in whole or in part, because the alleged damages were caused by the acts or omissions of third parties for which Optum Rx is not responsible.

- 11. Plaintiffs' claims may be barred, in whole or in part, to the extent that Plaintiffs have failed to join necessary parties.
- 12. Plaintiffs' claims may be barred, in whole or in part, to the extent Plaintiffs and/or Mr. Schmidtknecht failed to mitigate any damages.

Optum Rx has or may have other defenses which are not known at this time, but which may be ascertained in the future. Optum Rx reserves the right to assert each and every such other defense that may be ascertained.

WHEREFORE, Optum Rx denies that Plaintiffs are entitled to judgment against it and specifically denies that it is liable to Plaintiffs in any way. Optum Rx therefore demands judgment in its favor and such other relief as this Court deems just and proper.

Respectfully submitted,

Dated: August 22, 2025.

FOLEY & LARDNER LLP

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Attorneys for Defendant OptumRx, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below, the foregoing document was electronically filed with the Clerk of Court and served on all counsel of record using the Court's CM/ECF system.

Dated: August 22, 2025 /s/ Matthew D. Krueger

Matthew D. Krueger